K062727

510(k) SUMMARY of Safety and Effectiveness

I. Applicant Information:

Date Prepared:	August 19, 2006
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	Scott Cundy Senior Director – Regulatory & Clinical Affairs
Telephone Number:	(763) 391-9941
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OCT 11 2006

II. Device Information:

Trade Name:	Cardioblate Navigator™
Common Name:	Tissue Dissection Device
Classification Name:	Lamp, Surgical
Classification:	Class II, 21 CFR 878.4580
Product Code:	FTD
Predicate Device:	AtriCure® Wolf *dissector*™ 510(k) No. K041681, Reg. No. 878.4580; Product Code: FTD

Device Intended Use: The AtriCure Wolf *dissector*™ is intended to dissect soft tissue during general, ENT, thoracic, urological, and gynecological surgical procedures. The Dissector's battery-powered light source is used to navigate soft tissue for identification of anatomic structures.

Device Description:	The Medtronic Navigator® tissue dissection device is a single-use, hand-held surgical tissue dissector with an integral light source.
Intended Use:	The Medtronic® Cardioblate® Navigator™ Tissue Dissection Device is intended to dissect soft tissue during general, ENT, thoracic, urological, and gynecological surgical procedures. The device's battery-powered light source is used to navigate soft tissue for identification of the tip location around anatomic structures.
Contraindications:	None.
Comparison to Predicate Device(s):	The Cardioblate® Navigator™ device is substantially equivalent to the AtriCure Wolf *dissector*™, cleared in K041681, in terms of materials, use and application. The two devices are both hand held surgical dissectors with articulating tips and an integral light source (LED) for use in visually identifying internal tissue structures.
Test Data:	Verification and validation testing confirms that functional characteristics are substantially equivalent to the predicate device cited. This included clip strength and clip deployment angle. All test data obtained satisfied the documented product and performance specifications. In addition, the device meets the requirements for Medical Electrical Equipment: General Requirements (IEC 60601-1).
Summary:	Based upon the technical information, intended use, *in vitro*, *in vivo*, and clinical performance information provided in previous pre-market notifications, the Cardioblate® Navigator™ described in this submission has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2006

Medtronic, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K062727
Trade/Device Name: Medtronic Cardioblate® Navigator Tissue Dissection Device, Model 68015
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 29, 2006
Received: October 2, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

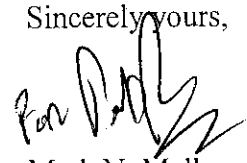
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K062727

Device Name: Medtronic Cardioblate® Navigator Tissue Dissection Device, Model 68015

Indications for use:

The Medtronic® Cardioblate® Navigator™ Tissue Dissection Device is intended to dissect soft tissue during general, ENT, thoracic, urological, and gynecological surgical procedures. The device's battery-powered light source is used to navigate soft tissue for identification of the tip location around anatomic structures.

Prescription Use x **(Part 21 CFR 801 Subpart D)** OR **Over-The-Counter-Use** _____ **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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